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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,316	02/09/2005	Nicholas Peter Franks	YOUZ 2 00109	6458
27885	7590	06/11/2007		
FAY SHARPE LLP 1100 SUPERIOR AVENUE, SEVENTH FLOOR CLEVELAND, OH 44114			EXAMINER ARNOLD, ERNST V	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 06/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,316	Applicant(s) FRANKS ET AL.	
	Examiner Ernst V. Arnold	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/9/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-20 are pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Comment: Please insert at the beginning of the specification: This Application is a 371 of PCT/GB03/03391 filed on 08/05/2003 and claims benefit to foreign application GB 0218153.5 filed on 08/05/2002.

Claim Rejections - 35 U.S.C. §§ 101 and 112, Second Paragraph

The following are quotations of 35 U.S.C. §§ 101 and 112, second paragraph, respectively, which form the basis of the claim rejections as set forth under this particular section of the Official Action:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. § 101 as being drawn to use claims, which are non-statutory process claims, as defined in 35 U.S.C. § 101. See, *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967). In addition, claims 1-10 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, a claim is rendered

Art Unit: 1616

indefinite when said claim merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP 2175.03(q). As a result, the Applicants are respectfully required to redraft the aforementioned use claims as statutory process claims that delimit active, positive steps on how to use a composition according to the invention as originally filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Ohashi et al. Anesthesiology 2002, 96, A1291.

Ohashi et al. disclose treating newborn Fischer rats, to test the antinociceptive effect of xenon, with either air or xenon ($\pm 75\%$ v/v). Air is a diluent and carrier for the xenon. Thus claims 11 and 13 are anticipated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1616

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukura et al. (Prog. Neuro-Psychopharmacol. & Biol Psychiat. 2000, 24, 1357-1368).

Fukura et al. disclose treatment of pregnant rats and neonatal rats with anesthetic xenon gas mixture (70% xenon 30% oxygen) (Abstract and Page 1359, Exposure to Anesthetic gases). Fukura et al. specifically examined the effect of xenon on the fetal rat brain thus anticipating instant claims 11 and 12 (Page 1359, Preparation of isolated growth cone Particles). Oxygen is a diluent thus anticipating instant claims 13 and 17. Fukura conclude that xenon is safe for perinatal neuronal development (Abstract).

Claim Rejections - 35 USC § 102

Claims 12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lane et al. Science 1980, 210(4472), 899-901).

Lane et al. disclose treating pregnant Sprague-Dawley rats with 70-75% v/v xenon and oxygen gas mixture and examined 160 fetuses (Page 900, Table 1 group D and right column). Oxygen is a diluent/carrier. It is the Examiner's position that the rat fetuses received any beneficial analgesic effect of the xenon gas mixture administered to the parent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukura et al. (Prog. Neuro-Psychopharmacol. & Biol Psychiat. 2000, 24, 1357-1368) in view of Georgieff (US 6,197,323) and Fishman (US 5,099,834) and Ohashi et al. Anesthesiology 2002, 96, A1291.

Applicant claims a method of providing analgesia in a newborn and in a fetal subject comprising administering a therapeutically effective amount of xenon.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The references of Fukura et al. and Ohashi et al. are described in detail above and those discussions are hereby incorporated by reference.

Georgieff teaches liquid anesthetic lipophilic gas preparations and methods of inducing analgesia comprising xenon and in a fatty emulsion (excipient/carrier) that can be administered intravenously or by inhalation (Abstract; column 9, lines 10-16; column 10, lines 22-65 and claims 16). Georgieff teaches ointments and creams which can be applied to the damaged tissue thus reading on transdermal application (column 9, lines 40-54).

Fishman teaches administration of xenon gas mixtures, from 60 to 78.5 mole percent xenon, to women of childbearing age (Abstract and claims 1-14). Fishman teaches that nitrous oxide is toxic to a fetus (column 1, lines 49-60).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Fukura et al. do not expressly teach a 20 to 70 % v/v xenon/air mixture; administration of xenon in the form of a lipid emulsion or where xenon is administered intravenously, neuraxially or transdermally.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

Art Unit: 1616

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a xenon gas mixture of 20 to 70% v/v xenon air, as suggested by Ohashi et al or administer the xenon in the form of lipid emulsion intravenously, as suggested by Georgieff, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Ohashi et al. suggest $\pm 75\%$ xenon/air mixture and it is merely routine optimization to arrive at the instantly claimed 70% xenon/air mixture. One of ordinary skill in the art would recognize other means of providing analgesia to a patient such as intravenous administration of xenon in a carrier as taught by Georgeiff. One of ordinary skill in the art would be motivated to use xenon, in such alternative forms in addition to inhalation, because nitrous oxide is taught by Fishman to be toxic to a fetus. So, one of ordinary skill in the art would be motivated to administer a therapeutically effective amount of xenon to women of childbearing age. The route of administration is easily determined by one of ordinary skill in the art. The fetus would intrinsically benefit from any analgesic properties of the gas.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

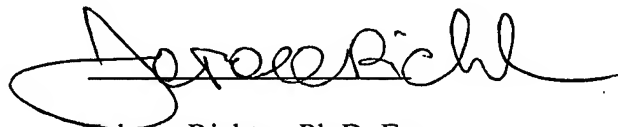
Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616

A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized loop at the beginning.

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
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